CROMPTON | SEAGER | TUFTE | LLC
Patent, Trademark & Copyright Attorneys

1221 Nicollet Avenue, Suite 800
Minneapolis, Minnesota 55403-2420
Phone 612.677.9050
Fax 612.359.9349

FAX TRANSMISSION COVER LETTER

TO: Commissioner for Patents
Attn: Mail Stop Appeal Brief - Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DATE: September 30, 2005
FROM: David M. Crompton
OUR REF: 1001.1258101
TELEPHONE: 612-677-9050

Total pages, including cover letter: 15

PTO FAX NUMBER: 571-273-8300

If you do NOT receive all of the pages, please telephone us at (612) 677-9050, or fax us at (612) 359-9349.

Title of Document(s) Transmitted: REPLY BRIEF
Applicant: Michael S.H. Chu et al.
Serial No.: 09/430,050
Filed: October 29, 1998
Group Art Unit: 1641
Our Ref. No.: 1001.1258101
Confirmation No.: 6707
Customer No.: 28075

Please charge Deposit Account No. 50-0413 as follows: **Fee Code** ____ **$**____. Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers, if appropriate. Please charge any additional fees or credit overpayment to Deposit Account No. 50-0413.

By: David M Crompton
Name: David M. Crompton
Reg. No. 36,772

I hereby certify that this paper is being transmitted by facsimile to the U.S. Patent and Trademark Office on the date shown below.

Kathleen L Boekley
Name: Kathleen L. Boekley

September 30, 2005
Date

RECEIVED
CENTRAL FAX CENTER

SEP 30 2005

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re:	Michael S. H. Chu et al.	Confirmation No.:	6707
Serial No.:	09/430,050	Examiner:	A. Lam
Filing Date:	October 29, 1998	Group Art Unit:	1641
Docket No.:	1001.1258101	Customer No.:	28075
For:	SPLIT VALVE FOR PEEL-AWAY SHEATH		

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY BRIEF

CERTIFICATE OF FACSIMILE TRANSMISSION UNDER 37 C.F.R. §1.8 (1(i)(B))
I hereby certify that this correspondence is being transmitted by facsimile to the United States Patent and Trademark Office at 571-273-8300 on the date shown below.

Kathleen L. Boekley
Type or print name of person signing certification

Kathleen L Boekley — September 30, 2005
Signature — Date

Dear Sir:

In response to the Examiner's Answer in the pending appeal of the above-referenced case, Appellants submit the following remarks:

REMARKS

The Examiner took several positions in the Examiner's Answer that are contrary to settled patent law and the facts of this case. Most significantly, Appellants will address several areas where the Examiner has a fundamental misunderstanding of the inherency doctrine. Also, a new argument with respect to an element of claim 12 was raised by the Examiner in the Answer. A response to this argument is included in this Reply Brief. Further, the Examiner mischaracterized several assertions that were made by Appellants in the Appeal Brief. These mischaracterizations will also be addressed.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *See Verdegaal Bros. v Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) and M.P.E.P. §2131. Throughout prosecution of this application, the Examiner has stated that Heck, U.S. Patent No. 6,083,207 contains each and every element of the pending claims. However, Heck fails to disclose every element of the pending claims.

Claim 1 is directed to a valve for a tubular peel-away sheath. Claim 1 recites, among additional elements, the following structural elements:

> a compressible valve sleeve having a proximal end, a distal end, and a lumen adapted to receive a distal portion of a medical device; and
>
> means for compressing said valve sleeve for restricting any fluid flow from said peel-away sheath lumen through said valve and valve sleeve lumen, said proximal end of said compressible valve sleeve extending proximal of said means for compressing said valve sleeve.

It can be seen that claim 1 requires the presence of a means for compressing a valve sleeve and a compressible valve sleeve. Heck does not describe at least these two elements.

A means for compressing is not present, either expressly or inherently, in the Heck disclosure. Appellants cannot locate, and the Examiner has failed to point out, an express statement that discloses such an element. However, the Examiner continues to insist that the compressing means is inherently present in the Heck disclosure. There are at least two significant errors in the Examiner's use of the inherency doctrine in this case.

The standards that the Examiner must comply with in showing the presence of an inherent element are well established. Showing that an element is inherent requires showing that the element must necessarily be present. *See* M.P.E.P. §2112. "The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *See* M.P.E.P. §2112, part IV (*citing In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)). In not providing any evidence that such an element is necessarily present, the Examiner has erred in finding that this element is inherent.

Additionally, the Examiner has made a significant error in placing the burden of proof on Appellants to prove that this element is not inherently present. For example, in paragraph 3 of page 8 of the Examiner's Answer, the Examiner states "Appellant has not pointed to any particular passage in Heck to support the assertion that a hemostasis valve does not inherently or otherwise compress a device that is passed through the body of the valve." (As we will discuss later in this paper, Appellants contest this statement in that ample evidence has been presented showing that Heck does not inherently disclose this element. This evidence will again be summarized in this Reply Brief.) However, Appellants assert that a case for inherency has never been made in the first instance, and case law states that the Examiner has the burden to do so. "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or

technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *See* M.P.E.P. §2112, Part IV, *citing Ex parte Levy* 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (first emphasis added, second emphasis in original). The Examiner has not provided evidence to show that this element must be present, and has therefore failed to meet the required burden of proof.

Whereas the Examiner has not produced evidence to show that Heck inherently discloses a compressing means, Appellants have shown that this element is not inherent. Appellants have given multiple examples of medical texts and patents that are cited in Heck that describe standard hemostasis valves. Appellants have also provided passages from Heck itself that support these standard definitions. Even though Appellants are not required to provide such proof, Appellants' evidence shows that Heck does not compress a device that is being passed through the valve.

Appellants have provided sources that show that the standard definition of a hemostasis valve is a valve that seals around a device, and does not compress the device in order to create a seal. As a general rule, "words in patent claims are given their ordinary meaning in the usage of the field of the invention, unless the text of the patent makes clear that a word was used with a special meaning." *Toro Co. v White Consolidated Ind., Inc.*, 199 F.3d 1295, 1299, 53 USPQ2d 1065, 1067 (Fed Cir. 1999). These legal concepts from M.P.E.P. §2111.01 and the cases cited therein have not been followed by the Examiner, causing a misinterpretation of Heck.

Applicants have offered descriptions of hemostasis valves from medical texts, the definition of a hemostasis valve from the patents cited in Heck, and the description given of a hemostasis valve in the Heck patent. All of these sources point to one conclusion: that a standard

hemostasis valve does not create a seal by compressing that which is being passed through it. According to M.P.E.P. §2111.01 and *Toro*, Heck must be read to use this standard definition unless Heck clearly indicates an alternate definition, which it does not.

The medical literature cited by Appellants helps illuminate the standard definition of a hemostasis valve as a valve that seals around a device. Appellants presented an example of such literature in an Office Action Response dated September 29, 2003. This source states that guide catheters or suction thrombectomy catheters can be passed through a hemostasis valve, and the valve seals around the devices. A guide catheter must be kept open for another device to pass through it, and a suction thrombectomy catheter must be kept open in order to perform the suction procedure through the lumen. The seal that is created by a hemostasis valve is a seal around the device that is being passed through the valve, and the valve is not designed to destroy the usefulness of any such device by compressing it.

In addition, an important attribute of a hemostasis valve is that a device can be passed through the valve easily, allowing the clinician to feel the progress of the medical device through the valve and into the patient's vasculature. A reference that outlines this attribute of hemostasis valves was also included in the September 29, 2003 Office Action Response. These valves are not meant to compress devices because this would eliminate this advantage of hemostasis valves.

The prior art cited in Heck also shows that a hemostasis valve does not seal by compressing a device that is passed through the body of the valve. *See* the September 29, 2003 Response for an outline of these patents. Patents from the background section of Heck describe a hemostasis valve as sealing around any devices that are passed through the valve, and these patents do not mention compressing the device that is passed through the valve body. *See*

September 29, 2003 Response at page 7. Also, these patents from Heck reference a body of patents that further explain the operation of a conventional hemostasis valve (*see* September 29, 2003 Response at pages 7-10 for more detail on these references). These patents describe hemostasis valves as sealing around a device. Some of these references include drawings that depict hemostasis valves being passed through the valve, and none of these drawings show the device being compressed. Appellants could not find any language or drawings in these background patents that compressed a device that was being passed through a hemostasis valve. These descriptions consistently indicate that hemostasis valves seal around a device.

In response to these sources, the Examiner stated, without citing any express language in Heck in support of the assertion, that these references that define the standard definition of a hemostasis valve are "irrelevant," because the Heck device "operates differently." *See* page 6 of the December 31, 2003 Office Action. This statement is the logical opposite of the holding of *Toro*, which states that a standard definition in the art is relevant, and should be followed unless there is clear language in the patent language that indicates intent of the patentee to depart from the standard definition. Heck does not contain any such language.

As stated above, the Examiner did not cite any language from Heck that even tends to indicate (much less clearly show) that Heck intended to use anything other than the standard definition of a hemostasis valve. In contrast, Appellants have cited multiple references from Heck that reinforce, rather than contradict, the standard definition of a hemostasis valve. This evidence presented from Heck shows that the Heck hemostasis valve functions like a conventional hemostasis valve, sealing around and not compressing a device.

Column 6, lines 43-53 of Heck was cited by the Appellants to show that the Heck hemostasis valve acts similarly to other hemostasis valves. This language states that the valve should be made of soft material that does not exert excessive force on a device that is being passed through the valve. Further, Appellants also cited Column 5, lines 53-59, which also speaks to the Heck valve material being soft and speaks to Heck using "conventional hemostasis valve materials." In response, the Examiner has made a baseless assertion that the "whole purpose" (*See* the text of the April 11, 2003 Advisory Action) of the Heck valve is to compress a device. The Examiner also stated, again without supporting reasoning, that given the structure of the hemostasis valve, the catheter "would be" compressed (*see* Examiner's Answer, page 10).

However, the Examiner does not present any explanation, other than assertions without reasoning, as to why the structure of Heck inherently compresses a device. The Examiner also does not explain why the disclosure of Heck would speak to preventing the use of extra force and using soft materials when, in the Examiner's words, the "whole purpose" is to compress a device. Instead, on page 12, second paragraph of the Examiner's Answer, the Examiner again improperly places the burden of proof on Appellants to prove that the inherent element is not present in Heck, and makes another assertion, without supporting reasoning, that the catheter is compressed. These passages from Heck reinforce that the Heck hemostasis valve does not contain a means for compressing, but instead functions as a standard hemostasis valve and seals around the device.

Appellants also cited column 2, lines 14-32 of Heck, which states that it is undesirable to pinch or squeeze the device. This language shows that Heck is speaking to the same design as the standard definition of a hemostasis valve, which is to seal around and not compress a device.

The Examiner's response was that this passage refers to compression by an operator, not by the valve. However, the Examiner did not indicate why language in Heck would speak to not wanting to compress a device between the fingers of an operator, and then compress the device in the valve, causing the same problems that column 2, lines 14-32 of Heck state should be avoided.

In light of all of this evidence and legal doctrine presented by Appellants, the Examiner has insisted, without citing any language from Heck or other sources that expressly states as such, that the Heck hemostasis valve "operates differently" (December 31, 2003 Office Action at page 6) than these devices, that Heck "must" compress a device that is being passed through the valve (June 30, 2003 Office Action at page 7), that a means for compressing is "required" (April 11, 2003 Advisory Action) and that the "whole purpose" of Heck is to compress a device (April 11, 2003 Advisory Action).

In one passage, the Examiner states that Heck discloses a valve, and a valve cuts off flow. From this, the Examiner extends the argument to say that the Heck valve must compress a device because it is a valve. *See* page 6 of the June 30, 2003 Office Action. However, just because Heck is a valve, it does not mean that it inherently has a means for compressing a valve sleeve. The fact that Appellants' examples of standard hemostasis valves do not compress a device belies the Examiner's argument on this point. If a valve must compress a device in order to form a seal, all of the prior art hemostasis valves would also do so. Because the background patents cited in Heck and the texts cited by Appellants do not have a means for compressing, it cannot be said that a hemostasis valve must necessarily contain such an element. Thus, this element is not inherently present in Heck.

Further, in light of all of the evidence cited by Appellants, it is somewhat puzzling that the Examiner quoted, then dismissed, column 9, lines 31-34 as the "most relevant" disclosure referring to a hemostasis valve:

> Because the hemostasis valve sections are forced together, the partitioned hemostasis valve acts like a conventional hemostasis valve, minimizing the amount of blood loss during the procedure.

(Quoted in the Examiner's Answer at page 8 and again at page 11) First of all, this quotation actually reinforces that Heck acts like a standard hemostasis valve. Obviously, the phrase "acts like a conventional hemostasis valve" would indicate to one of ordinary skill in the art that the Heck valve does, in fact, act like a conventional hemostasis valve. Instead, the Examiner makes a strained interpretation of this passage, stating, "the Heck valve acts like a conventional hemostasis valve in that it minimizes the amount of blood loss." *See* page 9 of the Examiner's Answer. Further, the Examiner goes on to state that this passage "does not state or imply that the Heck valve does not compress a device that that is passed through it." Again, rather than offering evidence that a "means for compressing" must necessarily be present in Heck, the Examiner improperly puts the burden of proof on Appellants (a burden which the Appellants have actually met), and does nothing to show the presence of the inherent element.

In summary, a "means for compressing" is not disclosed expressly or inherently in Heck. First, Heck does not expressly disclose an element that could be a "means for compressing." In fact, the Heck hemostasis valve is defined as NOT compressing a device. A standard hemostasis valve does not compress a device, and *Toro* states that this standard definition must be used unless it is expressly contradicted. Heck actually reinforces rather than contradicts this standard definition. Further, a "means for compressing" is not inherently present in Heck. Such an

element must necessarily be present, and with Heck actually defining a valve that does not compress, it is not necessarily present. Also, examples of hemostasis valves without a means for compressing show that a means for compressing is not a necessary element of such a valve. The Examiner must present evidence of an inherent element, and the Examiner has not done so. A "means for compressing" is simply not present in Heck.

Further, Heck does not contain a compressible valve sleeve. In the Examiner's Answer it is stated, without actually citing any language in support of this contention, that a catheter that is in the Heck hemostasis valve would be compressed. *See* page 9 of the Examiner's Answer. This seems to stem from the Examiner's reassertion "that the operation of the Heck device as described by Heck discloses that a catheter is compressed in the device." *See* page 9 of the Examiner's Answer. However, Examiner has not shown that Heck has a "means for compressing." Correspondingly, without a "means for compressing" present, a compressible element cannot be shown in the disclosure of Heck. Again, blanket assertions do nothing to satisfy the Examiner's burden of proof to show that a "means for compressing" is inherently present. If there is no "means for compressing," the Examiner cannot show that there is a compressible element in Heck.

In addition, Appellants have argued that the disclosure of a catheter in Heck would not be interpreted by one of ordinary skill in the art as a compressible element of Heck. "Claim terms are presumed to have the ordinary and customary meanings attributed to them by those of ordinary skill in the art." *See* M.P.E.P. §2111.01, part II (*citing Sunrace Roots Enter. Co. v SRAM Corp.*, 336 F.3d 1298, 1302, 6 USPQ2d 1438, 1441 (Fed. Cir. 2003) and *Brookhill-Wilk 1, LLC v Intuitive Surgical, Inc.*, 334 F.3d 1294, 1298, 67 USPQ2d 1132, 1136 (Fed. Cir. 2003).

Unless there is a clear statement to the contrary in Heck, one of ordinary skill in the art would interpret the catheter as a standard catheter. Because compressing a catheter as asserted by the Examiner would destroy much of the usefulness of the catheter (steerability of the catheter, ability to pass devices through the catheter, ability to transport fluids through the catheter, etc.), one of ordinary skill would not interpret a standard catheter as a compressible element in Heck. This is reinforced by the language in column 2, lines 14-32, which indicate it is undesirable to crush or pinch a catheter shaft. According to *Sunrace* and *Brookhill-Wilk*, the plain meaning that one of ordinary skill in the art would attribute to the catheter disclosed in Heck must be deferred to unless Heck clearly states otherwise. Heck does not clearly state an intention to depart from this definition.

Page 9, paragraph 3 of the Examiner's Answer states that the "Examiner is not asserting that one skilled in the art would use a catheter in place of a compressible valve sleeve." The next sentence seemingly then states that the Examiner is asserting that the catheter in Heck is a compressible element, contrary to the plain meaning that one of ordinary skill in the art would give the word "catheter." Specifically, the Examiner states "the rejection is based on the catheter disclosed in Heck being considered the claimed compressible valve sleeve." Because such a conclusion is contrary to the plain meaning of the term, the Examiner has committed a legal error. For all of the above reasons, the Examiner has not shown that Heck contains a "compressible valve sleeve" or its structural equivalent.

In light of Heck lacking at least two elements of claim 1, the rejection of claim 1 should be reversed. In light of the presence of similar elements in independent claims 3, 12, and 15, and

because the dependent claims recite additional patentably distinct elements, the rejection of all of the claims should be reversed.

Appellants noted in the Appeal Brief that claim 12 recites a valve sleeve seat that receives an end of the compressible valve sleeve. Appellants stated that the valve sleeve seat was not present in Heck because, even if the device (300) were considered a compressible valve sleeve (which Appellants do not agree with, as stated above), Heck shows the device (300) extending all the way through the valve, which shows that there is not a valve sleeve seat. In the current Application, the valve sleeve distal end abuts this valve sleeve seat (32), and thus the valve sleeve seat does not allow the compressible valve sleeve to be inserted into the tube (202) beyond the valve sleeve seat. For this definition of a valve sleeve seat, *see* the specification at page 7, lines 8-9 and Figure 1.

The Examiner rebutted this argument by raising a point of argument that had not previously been raised in prosecution. Specifically, it was stated, "a proximal end of the catheter can be received in the claimed valve seat, which is indicated as element (50) in the rejection." *See* page 13 of the Examiner's Answer. There are at least two fatal flaws with the Examiner's statement. First, Heck does not actually or inherently disclose the subject matter that the Examiner is citing, as required for this claim to be anticipated by Heck. *See Verdegaal Bros. v Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) and M.P.E.P. §2131. The Examiner cannot possibly know if the proximal end of the catheter shaft could be inserted, or how that proximal end would interact with the valve of Heck, because Heck never speaks to inserting the proximal end of the catheter in the hemostasis valve.

Second, claim 12 recites a "valve body having a seat for mating to said proximal valve sleeve distal region." Thus, Examiner's statement that the proximal end of the catheter in Heck might be able to match up with something that might be called a valve sleeve seat is completely irrelevant. Because Heck lacks a valve sleeve seat as described in Heck and *Verdegaal* has stated that a reference must contain all of the claim elements, claim 12 is not anticipated by Heck, and the rejection of claim 12 should be reversed. Because they are dependent on claim 12 and because they contain additional patentably distinct elements, the rejection of claims 13 and 14 should also be reversed.

The Examiner has also mischaracterized several of Appellants' statements from the Appeal Brief. On the last paragraph of page 11 of the Examiner's Answer, the Examiner mischaracterizes one element of Appellants' argument. Appellants have argued that the disclosure of the device sealing aroumd a pacemaker lead reinforces that the Heck hemostasis valve does not compress, but seals around devices that are passing through the valve. Appellants raised this point of argument to rebut the Examiner's assertion that the valve in Heck inherently creates a seal by compressing a device in the valve. A pacemaker wire would not be compressed, and the valve would seal around the wire. The disclosure in Heck of the valve sealing around a device (a pacemaker lead) refutes the Examiner's assertion that the Heck device must necessarily contain a "means for compressing," and therefore this element is not inherently present in Heck.

On page 12, first paragraph, the Examiner mischaracterizes another of Appellants' arguments. Appellants argued that language in Heck states that it would be undesirable for a physician to pinch or squeeze the catheter shaft because it will likely compromise the usefulness

of the catheter. The Examiner seems to argue that this passage cited by Appellants is irrelevant because the passage speaks to a physician, and not the valve, not pinching the catheter shaft. However, Appellants raised this point of argument because it is additional evidence that the valve is not meant to, and therefore does not expressly or inherently, compress a device being passed through it. As mentioned earlier in this paper, the Examiner did not indicate why language in Heck would speak to not wanting to compress a device between the fingers of an operator, and then compress the device in the valve, causing the same problems that column 9, lines 14-32 of Heck state should be avoided.

For all of the above reasons, the rejection of the current claims should be overturned.

Respectfully submitted,

Michael S. H. Chu et al.

By their Attorney,

Date: 9/30/05

David M. Crompton, Reg. No. 36,772
CROMPTON, SEAGER & TUFTE, LLC
1221 Nicollet Avenue, Suite 800
Minneapolis, Minnesota 55403-2420
Telephone: (612) 677-9050
Facsimile: (612) 359-9349